



ENZYMATIC THERAPY
INCORPORATED

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INTEGRATIVE THERAPEUTICS INC.™

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9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 ♦ F: 503.582.0467

**ENZYMATIC THERAPY®
&
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

November 16, 2004

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	End Fatigue Pain Formula* combines white willow bark, boswellia, and cherry fruit extract in a unique, exclusive formula that is well-tolerated by individuals seeking relief for occasional muscle pain due to overuse.*	Boswellia serata gum resin extract standardized to contain 70% boswellic acids, Sweet Cherry (Prunus avium) Fruit Extract 10:1, White Willow (Salix alba) Bark Extract standardized to contain 30% Salicin

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

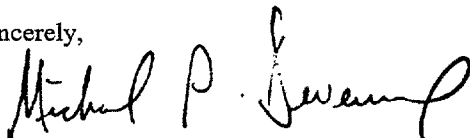
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11-16-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

97S 0162

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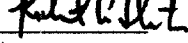
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	White willow (Salix alba) bark's key ingredient is salicin, a glycoside that is converted into salicylic acid by the liver. Salicylic acid from white willow blocks the release of prostaglandins, compounds associated with pain and inflammation generated by the cyclooxygenase (COX) pathways.*	White Willow (Sulix alba) Bark Extract standardized to contain 30% Salicin

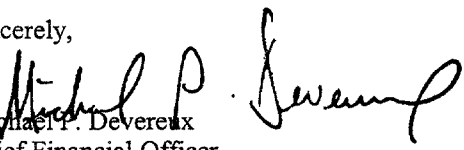
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	Beneficial support has been noted in multiple clinical trials, including a recent study in which 50% of participants (compared to 6% of the placebo group) reported relief of occasional pain due to overuse.*	White Willow (Sulix alba) Bark Extract standardized to contain 30% Salicin

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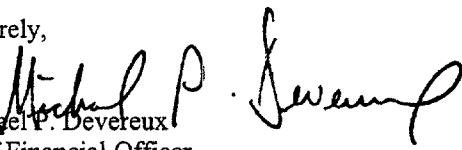
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	In a study of willow bark for joint support, more adverse events were reported in the placebo group than in the group receiving the white willow bark extract.*	White Willow (Salix alba) Bark Extract standardized to contain 30% Salicin

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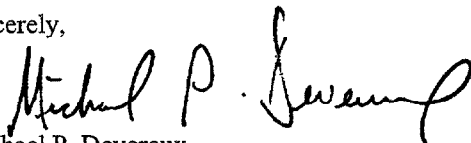
Robert Doster

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Date: 11-17-04

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Sincerely,


Michael P. Devereux
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	Boswellia serrata inhibits the production of leukotrienes, powerful chemical compounds that are involved in the inflammatory response.* Leukotrienes are synthesized by 5-lipoxygenase (LOX) enzymes, another pathway responsible for initiation, promotion, and progression of inflammatory events.* Recent research suggests that inhibition of lipoxygenase-generated leukotrienes may also provide support of healthy cell development.*	Boswellia Serata Gum Resin Extract standardized to contain 70% boswellic acids

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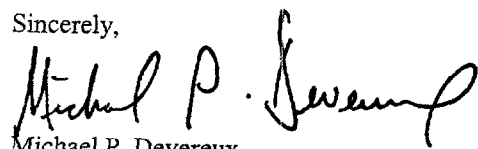
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11-17-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" and last name "Devereux" clearly legible, and a middle initial "P." in between.

Michael P. Devereux
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	White willow bark was shown in a clinical trial to provide significant benefit for joint support, with no benefit reported in the placebo group.*	White Willow (Salix alba) Bark Extract standardized to contain 30% salicin

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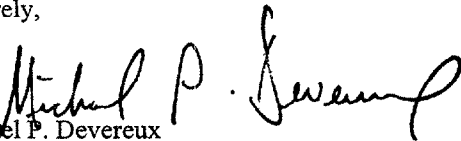
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	Clinical study results showed key actives in cherry fruit modulate inflammation pathways.*	Sweet Cherry (Prunus avium) Fruit Extract

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By: _____

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

11-19-04

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Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	A recent randomized, double-blind, placebo controlled clinical study of Boswellia serrata produced a significant decrease in occasional pain and stiffness due to overuse.* All the participants continued to take boswellia even after the completion of the study. Side effects were mild and did not result in withdrawal of treatment.*	Boswellia Serata Gum Resin Extract standardized to contain 70% boswellic acids

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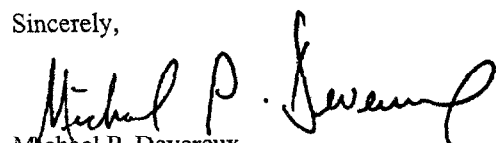
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue™ Pain Formula*	Cherry fruit extract has been demonstrated to support healthy uric acid levels, a factor linked to healthy joints.*	Sweet Cherry (Prunus avium) Fruit Extract

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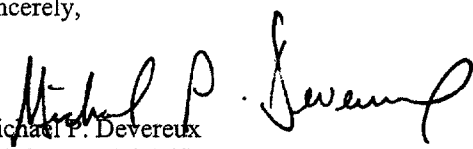
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Michael P. Devereux
Chief Financial Officer